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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/244,792	02/05/99	IACONO A	P32130

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HM12/0410

EXAMINER	
TRAVERS,R	
ART UNIT	**PAPER NUMBER**
1614	8

DATE MAILED: 04/10/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.	Applicant(s)
09/244,792	Iacono
Examiner	**Group Art Unit**
RUSSELL TRAVERS	1614

☒ Responsive to communication(s) filed on *Jan 18, 2000*.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *19-47* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *19-47* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The amendment filed January 8, 2000 has been received and entered into the file.

Applicant's arguments filed January 8, 2000 have been fully considered but they are not deemed to be persuasive.

Claims 19-47 are presented for examination. Applicant's attention is directed to a failure to provide a claim 31, thus, presented claims 32 and greater have been renumbered.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19, 21, 25, 28, 30, 32, 35, 37, 38, 40, 41, 44, 46 and 47 are rejected under 35 U.S.C. § 102(b) as being anticipated by Gilbert et al, of record.

Claims 20, 26, 28, 30, 31, 35, 36, 38, 39, 41, 43, 44 and 46-47 are rejected under 35 U.S.C. § 102(b) as being anticipated by Knight et al or Waldrep et al, of record.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 20-47 are rejected under 35 U.S.C. § 103 as being unpatentable over Adjei et al and Waldrep et al, in view of Gilbert et al, Knight et al and Applicant's admission on the record.

Adjei et al, Waldrep et al, Gilbert et al, Knight et al and Applicant admits on the record the claimed compounds as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These medicaments are taught as useful for treating graft rejection, inflammation and those conditions herein claimed and disclosed. Claims 22, 23, 24, 27, 29, 33, 34, 42 and 45, and the primary references, differ as to:

1) dosage levels herein claimed.

Determining the active ingredient dosage level required to effect optimal therapeutic benefit is well within the Skilled Artisan's purview and the benefits of achieving such maximization obvious, to said skilled artisan. Attention is directed to

Adjei et al (column 8) teaching the normal practice of dosage maximization by the attending medical professional. The claims merely recite the obvious employment of old and well known active ingredients, carriers and excipients. Thus, the only issue presented in the instant application is the obviousness of the claimed compositions and therapeutic methods.

Claim 47 specifically requires a pharmaceutical composition wherein the particle size is 0.1-2.0 microns. Adjei et al teach particle sizes encompassing this claimed range.

Claim 43 requires propylene glycol carrier or excipient to administer the active ingredients. This carrier is taught as old and well known by Waldrep et al (see column 4, line 59).

Attention is directed to claims reading on cyclosporine powder, at a particular size range, absent carriers or excipients. Such claims read on the compounds herein disclosed, and taught as old by the Examiner cited prior art.

RESPONSE TO ARGUMENTS

Examiner cited prior art teaches the claimed compounds alone, or with simple carriers as useful for treating those graft rejections herein claimed. Failure to claim such simple and fundamental medicament administration procedures fail to diminish those teachings. Additionally, Applicant appears to be arguing a much more limited invention than herein claimed; rebuttal arguments based on unclaimed limitations are

moot. If medicament application produces an expected therapeutic outcome, that therapeutic outcome is anticipated; regardless the recitation of that inherent therapeutic benefit.

The instant claims are directed to employing an organic solvent, a very broad carrier recitation for such a crowded field. A simple oil would meet an "organic solvent" limitation.

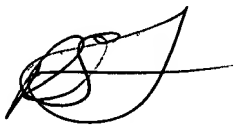
As stated above, the discovery of a mechanism by which a drug is taken up by a biological system fails to distinguish over the same administration system before such discoveries.

As stated above, rebuttal arguments based on unclaimed limitations are moot. In the instant case, liposome limitations are not present in the instant claims. Applicant's claims read on any organic carrier, such as liposomes, or dry powder carried by air. Attention is directed to Waldrep et al teaching dry particle cyclosporine administration (see column 1). Applicant's presented claims are extremely broad, thus, are easily met by the Examiner cited prior art. Those inventions argued appear to be much more limited than those claims presented. Examiner can not read limitations from the specification into the presented claims. Only limitations specifically recited in the presented claims will serve to distance the envisioned invention from the cited prior art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.



Russell Travers
Primary Examiner
Art Unit 1614